

Supplementary Online Content

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eTable. Secondary Outcomes and Symptoms Through 48 Weeks After Randomization Among HIV-Infected Children Remaining on a Ritonavir-Boosted Lopinavir-Based Regimen or Switched to an Efavirenz-Based Regimen

This supplementary material has been provided by the authors to give readers additional information about their work.

eTable. Secondary Outcomes and Symptoms Through 48 Weeks After Randomization Among HIV-Infected Children Remaining on a Ritonavir-Boosted Lopinavir-Based Regimen or Switched to an Efavirenz-Based Regimen

	N	Ritonavir-boosted Lopinavir	N	Efavirenz	P-Value
CD4 percentage, Mean (95% CI)					
Baseline	137	34.4 (33.3, 35.5)	138	35.0 (33.7, 36.2)	0.51
Week 24	140	34.5 (33.3, 35.6)	142	36.1 (34.8, 37.4)	0.07
Week 48	142	34.7 (33.6, 35.8)	136	37.5 (36.3, 38.8)	<.001
Change CD4 percentage from baseline, Mean (95% CI)					
Week 24	130	0.12 (-0.84, 1.08)	132	1.11 (0.15, 2.08)	0.15
Week 48	131	0.04 (-0.98, 1.07)	125	2.92 (1.94, 3.89)	<.001
CD4 count, Mean (95% CI)					
Baseline	137	1464 (1366, 1562)	138	1517 (1413, 1621)	0.47
Week 24	140	1377 (1289, 1465)	143	1397 (1306, 1489)	0.76
Week 48	143	1384 (1294, 1474)	137	1353 (1266, 1440)	0.62
Weight-for-age z-score, Mean (95% CI)					
Randomization	148	-0.81 (-0.96, -0.65)	150	-0.87 (-1.02, -0.72)	0.57
Week 4	146	-0.82 (-0.97, -0.66)	150	-0.81 (-0.97, -0.66)	0.97
Week 8	146	-0.81 (-0.97, -0.66)	148	-0.80 (-0.96, -0.65)	0.93
Week 16	147	-0.82 (-0.98, -0.67)	147	-0.77 (-0.93, -0.61)	0.64
Week 24	147	-0.81 (-0.96, -0.66)	147	-0.82 (-0.98, -0.66)	0.92
Week 32	147	-0.77 (-0.93, -0.62)	144	-0.80 (-0.95, -0.65)	0.83
Week 40	148	-0.78 (-0.93, -0.64)	144	-0.82 (-0.97, -0.66)	0.77
Week 48	147	-0.79 (-0.94, -0.63)	144	-0.81 (-0.96, -0.65)	0.86
Height-for-age z-score, Mean (95% CI)					
Randomization	148	-1.30 (-1.45, -1.15)	150	-1.36 (-1.52, -1.20)	0.62
Week 4	146	-1.30 (-1.45, -1.15)	150	-1.35 (-1.51, -1.20)	0.65
Week 8	146	-1.28 (-1.44, -1.12)	148	-1.36 (-1.52, -1.21)	0.46
Week 16	147	-1.25 (-1.40, -1.10)	147	-1.33 (-1.48, -1.17)	0.45
Week 24	147	-1.24 (-1.39, -1.09)	147	-1.31 (-1.46, -1.16)	0.54
Week 32	147	-1.26 (-1.42, -1.11)	144	-1.36 (-1.52, -1.20)	0.40
Week 40	148	-1.22 (-1.37, -1.06)	144	-1.30 (-1.45, -1.14)	0.49
Week 48	147	-1.21 (-1.37, -1.06)	144	-1.29 (-1.45, -1.12)	0.52

eTable. Secondary Outcomes and Symptoms Through 48 Weeks After Randomization Among HIV-Infected Children Remaining on a Ritonavir-Boosted Lopinavir-Based Regimen or Switched to an Efavirenz-Based Regimen (continued)

	N	Ritonavir-boosted Lopinavir	N	Efavirenz	P-Value
Highest grade^s hemoglobin after randomization, N (%)					
Grade 0	148	146 (98.7)	150	149 (99.3)	0.62
Grade 1		2 (1.4)		1 (0.7)	
Highest grade^s neutropenia after randomization, N (%)					
Grade 0	148	136 (91.9)	150	144 (96.0)	0.08
Grade 1		4 (2.7)		3 (2.0)	
Grade 2		5 (3.4)		1 (0.7)	
Grade 3		3 (2.0)		0 (0.0)	
Grade 4		0 (0.0)		2 (1.3)	
Highest grade^s alanine aminotransferase after randomization, N (%)					
Grade 0	148	139 (93.9)	150	120 (80.0)	0.003
Grade 1		8 (5.4)		16 (10.7)	
Grade 2		0 (0.0)		10 (6.7)	
Grade 3		1 (0.7)		3 (2.0)	
Grade 4		0 (0.0)		1 (0.7)	
Highest grade^s skin manifestation after randomization, N (%)					
Grade 0	148	135 (91.2)	150	130 (86.7)	0.17
Grade 1		12 (8.1)		14 (9.3)	
Grade 2		1 (0.7)		6 (4.0)	
Admitted to hospital after randomization, N (%)					
Yes	148	3 (2.0)	150	2 (1.3)	0.68
No		145 (98.0)		148 (98.7)	
Initiated on tuberculosis medication after randomization, N (%)					
Yes	148	0 (0.0)	150	2* (1.3)	0.50
No		148 (100.0)		148 (98.7)	
Seizure after randomization, N (%)					
Yes	148	0	150	2* (1.3)	0.50
No		148 (100.0)		148 (98.7)	

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	N	Ritonavir-boosted Lopinavir	N	Efavirenz	P-Value
Cough, N (%)					
Randomization	148	35 (23.7)	150	31 (20.7)	0.54
Week 4	146	25 (17.1)	150	24 (16.0)	0.80
Week 8	146	22 (15.1)	148	21 (14.2)	0.83
Week 16	147	26 (17.7)	147	33 (22.5)	0.31
Week 24	147	24 (16.3)	147	31 (21.1)	0.30
Week 32	147	28 (19.1)	144	20 (13.9)	0.24
Week 40	148	18 (12.2)	144	26 (18.1)	0.16
Week 48	147	28 (19.1)	144	15 (10.4)	0.04
At least once post-randomization	148	101 (68.2)	150	95 (63.3)	0.37
Fever or high temperature, N (%)					
Randomization	148	11 (7.4)	150	13 (8.7)	0.70
Week 4	146	13 (8.9)	150	15 (10.0)	0.75
Week 8	146	10 (6.9)	148	14 (9.5)	0.41
Week 16	147	8 (5.4)	147	15 (10.2)	0.13
Week 24	147	11 (7.5)	147	10 (6.8)	0.82
Week 32	147	7 (4.8)	144	11 (7.6)	0.31
Week 40	148	4 (2.7)	144	6 (4.2)	0.54
Week 48	147	8 (5.4)	144	2 (1.4)	0.10
At least once post-randomization	148	56 (37.8)	150	55 (36.7)	0.83
Loss of appetite, N (%)					
Randomization	148	8 (5.4)	150	14 (9.3)	0.27
Week 4	146	7 (4.8)	150	7 (4.7)	0.96
Week 8	146	12 (8.2)	148	8 (5.4)	0.34
Week 16	147	9 (6.1)	147	12 (8.2)	0.50
Week 24	147	8 (5.4)	147	5 (3.4)	0.40
Week 32	147	5 (3.4)	144	8 (5.6)	0.37
Week 40	148	3 (2.0)	144	7 (4.9)	0.21
Week 48	147	4 (2.7)	144	4 (2.8)	1.0
At least once post-randomization	148	47 (31.8)	150	43 (28.7)	0.56

eTable. Secondary Outcomes and Symptoms Through 48 Weeks After Randomization Among HIV-Infected Children Remaining on a Ritonavir-Boosted Lopinavir-Based Regimen or Switched to an Efavirenz-Based Regimen (continued)

	N	Ritonavir-boosted Lopinavir	N	Efavirenz	P-Value
Fatigue, loss of energy, weakness, N (%)					
Randomization	148	2 (1.4)	150	2 (1.3)	1.0
Week 4	146	1 (0.7)	150	1 (0.7)	1.0
Week 8	146	2 (1.4)	148	1 (0.7)	0.62
Week 16	147	2 (1.4)	147	4 (2.7)	0.68
Week 24	147	1 (0.7)	147	1 (0.7)	1.0
Week 32	147	1 (0.7)	144	1 (0.7)	1.0
Week 40	148	0 (0.0)	144	0 (0.0)	1.0
Week 48	147	1 (0.7)	144	2 (1.4)	0.62
At least once post-randomization	148	11 (7.4)	150	12 (8.0)	0.85
Diarrhea, N (%)					
Randomization	148	6 (4.1)	150	6 (4.0)	0.98
Week 4	146	7 (4.8)	150	7 (4.7)	0.96
Week 8	146	3 (2.1)	148	2 (1.4)	0.68
Week 16	147	5 (3.4)	147	4 (2.7)	1.0
Week 24	147	4 (2.7)	147	7 (4.8)	0.36
Week 32	147	2 (1.4)	144	4 (2.8)	0.44
Week 40	148	2 (1.4)	144	2 (1.4)	1.0
Week 48	147	4 (2.7)	144	2 (1.4)	0.68
At least once post-randomization	148	25 (16.9)	150	26 (17.3)	0.92
Headaches, N (%)					
Randomization	148	0 (0.0)	150	3 (2.0)	0.25
Week 4	146	2 (1.4)	150	4 (2.7)	0.69
Week 8	146	0 (0.0)	148	3 (2.0)	0.25
Week 16	147	2 (1.4)	147	4 (2.7)	0.68
Week 24	147	2 (1.4)	147	0 (0.0)	0.50
Week 32	147	1 (0.7)	144	0 (0.0)	1.0
Week 40	148	0 (0.0)	144	1 (0.7)	0.49
Week 48	147	1 (0.7)	144	0 (0.0)	1.0
At least once post-randomization	148	8 (5.4)	150	11 (7.3)	0.50

eTable. Secondary Outcomes and Symptoms Through 48 Weeks After Randomization Among HIV-Infected Children Remaining on a Ritonavir-Boosted Lopinavir-Based Regimen or Switched to an Efavirenz-Based Regimen (continued)

	N	Ritonavir-boosted Lopinavir	N	Efavirenz	P-Value
Trouble sleeping or nightmares, N (%)					
Randomization	148	3 (2.0)	150	5 (3.3)	0.72
Week 4	146	0 (0.0)	150	39 (26.0)	<.001
Week 8	146	1 (0.7)	148	6 (4.1)	0.12
Week 16	147	4 (2.7)	147	1 (0.7)	0.37
Week 24	147	1 (0.7)	147	0 (0.0)	1.0
Week 32	147	0 (0.0)	144	1 (0.7)	0.50
Week 40	148	0 (0.0)	144	1 (0.7)	0.49
Week 48	147	1 (0.7)	144	0 (0.0)	1.0
At least once post-randomization	148	6 (4.1)	150	44 (29.3)	<.001
Nausea, N (%)					
Randomization	148	5 (3.4)	150	6 (4.0)	0.78
Week 4	146	6 (4.1)	150	10 (6.7)	0.33
Week 8	146	1 (0.7)	148	11 (7.4)	0.004
Week 16	147	6 (4.1)	147	6 (4.1)	1.0
Week 24	147	4 (2.7)	147	7 (4.8)	0.54
Week 32	147	0 (0.0)	144	8 (5.6)	0.003
Week 40	148	5 (3.4)	144	3 (2.1)	0.72
Week 48	147	3 (2.0)	144	3 (2.1)	1.0
At least once post-randomization	148	26 (17.6)	150	42 (28.0)	0.03
Skin problems, such as rash, sores, dryness, N (%)					
Randomization	148	16 (10.8)	150	13 (8.7)	0.53
Week 4	146	11 (7.5)	150	15 (10.0)	0.45
Week 8	146	12 (8.2)	148	11 (7.4)	0.80
Week 16	147	11 (7.5)	147	14 (9.5)	0.68
Week 24	147	10 (6.8)	147	8 (5.4)	0.63
Week 32	147	9 (6.1)	144	13 (9.1)	0.35
Week 40	148	10 (6.8)	144	11 (7.6)	0.77
Week 48	147	10 (6.8)	144	11 (7.6)	0.78
At least once post-randomization	148	52 (35.2)	150	67 (44.7)	0.09

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	N	Ritonavir-boosted Lopinavir	N	Efavirenz	P-Value
Adherence with antiretroviral drugs based on medication return at all scheduled visits post-randomization, N (%)					
Ritonavir-boosted lopinavir Adherent Non-Adherent (>10% of medication returned)		656 (87.1) 97 (12.9)			
Efavirenz Adherent Non- Adherent (>10% of medication returned)				743 (84.2) 139 (15.8)	0.23
Lamivudine Adherent Non- Adherent (>10% of medication returned)		665 (91.7) 60 (8.3)		670 (90.7) 69 (9.3)	0.58
Abacavir or stavudine Adherent Non- Adherent (>10% of medication returned)		662 (87.5) 95 (12.5)		672 (87.8) 93 (12.2)	0.88

* The two children diagnosed with tuberculosis and developing seizures were not the same individuals.

§ Grades for toxicity were determined using the Division of AIDS Table for Grading the severity of adult and pediatric adverse events (December 2004).

P-values for continuous variables were calculated using t-tests and for all categorical variables except adherence using chi-squared tests. P-values for adherence were calculated using Generalized Estimating Equation (GEE) models. Denominators are as shown. Missing data were excluded.